K003284

510(k) Summary

JAN 17 2001

General Information

Classification	Class II
Trade Name	Phlebopump™ Model 1000
Submitter	Prevent Products, Inc. 1167 Ottawa Avenue West St. Paul, MN 55118 651-457-4385
Contact	Carol A. Garcia President

Intended Use

The Phlebopump™ Model 1000 is intended to enhance circulation in the lower leg to:

1. help prevent deep vein thrombosis
2. help prevent venous stasis and blood pooling in the legs
3. help the normal healing of leg ulcers and wounds
4. increase skin blood flow
5. reduce edema

Predicate Devices K959275 - Ankle Calf Exerciser Phlebopump (ACE/PP

Device Description

The Phlebopump™ Model 1000 is an easy-to-use compact portable device with motor driven paddles. The product is controlled either by staff or the patient via an air switch. Reusable (washable) cloth foot holders secure the patient's feet onto the paddles during use. The paddles are driven by the electric motor in a natural and gentle dorsiflex motion. The Phlebopump™ Model 1000 is intended to be comfortable and easy-to-use to minimize non-compliance during use.

Materials

All materials used in the manufacture of the Phlebopump™ Model 1000 are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included electrical safety, electromagnetic compatibility and air switch operation.

Summary of Substantial Equivalence

The Phlebopump™ Model 1000 is intended to enhance circulation in the lower leg. The indications for use as well as the materials used in the construction of this product are either identical or substantially equivalent to legally marketed predicate product, the A-V Impulse System. Prevent Products believes the Phlebopump™ Model 1000 is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2001

Ms. Carol A. Garcia
President
Prevent Products, Inc.
1167 Ottawa Avenue
West St. Paul, MN 55118

Re: K003284
Trade Name: Phlebopump™ Model 1000
Regulatory Class: II
Product Code: JOW
Dated: August 23, 2000
Received: October 19, 2000

Dear Ms. Garcia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), or for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003284

Indications for Use

510(k) Number (if known): This application

Device Name: Phlebopump™ Model 1000

Indications for Use: The Phlebopump™ Model 1000 is intended to enhance circulation in the lower leg to:

1. help prevent deep vein thrombosis
2. help prevent venous stasis and blood pooling in the legs
3. help the normal healing of leg ulcers and wounds
4. increase skin blood flow
5. reduce edema

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K003284

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use _ (Optional Format 1-2-96)

1-17-1

Division of Cardiovascular & Respiratory Devices
510(k) Number K003284